

Sharps Injury Control Program



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SHARPS INJURY CONTROL PROGRAM

I. EXECUTIVE SUMMARY

A. INTRODUCTION

"It is one of the happy incidents of the federal system that a single courageous state may, if its citizens so choose, ... try novel social and economic experiments...." Justice Louis Brandeis, 1932.

"We know that needleless devices and safe needle devices can save lives. We must do everything we can to protect the healthcare workers who have devoted their lives to keeping America healthy." Linda Rosenstock, MD, MPH, Director, National Institute for Occupational Safety and Health, 1999.

In 1996, Senator Mike Thompson introduced legislation, Senate Bill (SB) 2005 (Statutes of 1996, Chapter 683), that resulted in the establishment of the Sharps Injury Control Program. This bill inaugurated a statewide surveillance system, the first of its kind, that has documented and evaluated needlestick and other sharps injuries to healthcare workers in California. In 1998, Assemblywoman Carol Migden introduced Assembly Bill (AB) 1208 (Statutes of 1998, Chapter 999) requiring that the then current California Bloodborne Pathogens Standard include a provision that needleless systems and safety-enhanced needle devices be used in all healthcare settings. Thus California became the first state in the nation to implement a primary prevention program aimed at protecting healthcare workers from exposure to lethal and disabling bloodborne pathogens. Over the past two years, over 15 states have passed similar legislation. On November 6, 2000, President Clinton signed the Needlestick Safety Prevention Act, directing the Federal Occupational Safety and Health Administration to ensure more widespread use of safer medical devices to prevent dangerous sharps injuries. This report will provide a summary of the history, activities, and findings of the three-year pilot "Sharps Injury Control Program (SHARPS)," established and funded by SB 2005. It will also provide information on Department of Health Services (DHS) activities mandated by AB 1208. The initial 3-year pilot Sharps Injury Control Program ended June 30, 2000.

B. THE SHARPS INJURY CONTROL PROGRAM

The SHARPS Program is located in the Department of Health Services (DHS), Division of Environmental and Occupational Disease Control, Occupational Health Branch, and conducted under contract by the University of California, San Francisco, School of Nursing. Both SB 2005 and AB 1208 required the SHARPS Program to initiate activities aimed at reducing sharps injuries to healthcare workers. SHARPS addressed specific injury control issues for employers and employees in hospitals, home health agencies, and skilled nursing facilities. SHARPS successfully implemented all provisions stipulated by SB 2005 and AB 1208, focusing on five priority areas:

1. Development and analysis of a statewide occupational sharps injury registry, including development of a sharps injury log;
2. Completion of a statewide healthcare facility survey focusing on institutional data collection techniques and safety device use;
3. Education of healthcare institutions and providers about work practices found to be effective in reducing occupational sharps injuries;
4. Creation of a web-based, as well as a paper-based, list of needleless systems and safety-enhanced needle devices; and
5. Compilation and dissemination of resources for device evaluation.

C. SUMMARY OF MAJOR FINDINGS

Statewide Occupational Sharps Injury Registry

A total of 1,940 sharps-related injury reports from over 199 different health care institutions have been voluntarily provided to the Sharps Injury Registry (Registry). Of these, 91.8 percent were reported by hospitals. Approximately two-thirds (66.9 percent) of the injury reports were on non-standard forms, including hand written reports. The voluntary nature of the reports, as provided by SB 2005, combined with the use of non-standard forms and missing information, made analysis and interpretation of these data difficult. Drawing venous blood and giving injections through the skin each accounted for about 20 percent of all reported injuries. The Registry data documented ongoing work practices that have been prohibited since 1993 by the Cal/OSHA Bloodborne Pathogens Standard (Title 8, California Code of Regulations, Section 5193). For example, 6 percent of the injuries reported to the Registry occurred while recapping a needle.

Statewide Healthcare Facility Survey

Forty-seven percent of hospitals, home health agencies, and skilled nursing facilities responded to the healthcare facility survey. The survey collected information on sharps surveillance methods, use of safety-enhanced devices, and need for educational materials and/or technical assistance.

Most institutions record injury data in written format, making aggregate data analysis more difficult than if they were recorded electronically. However, almost all institutions collect information that assists them in describing the injury events.

Eighty-five percent of responding institutions and agencies reported that they needed additional educational materials regarding surveillance techniques, bloodborne pathogens, safety-enhanced devices, and selection and evaluation of devices. Only a minority of the respondents reported having experience evaluating new safety-enhanced devices, although hospitals did report significantly more experience than home health care agencies or skilled nursing facilities.

List of Needleless Systems and Needles with Engineered Sharps Injury Protection

The SHARPS Program, in cooperation with the Division of Occupational Safety and Health (Cal/OSHA) developed and compiled a “List of Needleless Systems and Needles with Engineered Sharps Injury Protection (List).” This List is available to assist employers in complying with regulatory changes, but also to assist them in device selection and evaluation. Over 60 devices are currently included on the List. In addition, the SHARPS Program created a Device Evaluation Resource guide for healthcare institutions and providers.

Service to Healthcare Institutions and Providers

The SHARPS Program developed a model Sharps Injury Log, educational brochures, assessment checklists, and fact sheets. In addition, Sharps staff provided expert assistance at conferences, training seminars, and telephone consultations to over 1,000 healthcare institutions and providers throughout California, as well as in other states, provinces, and countries.

BACKGROUND AND HISTORY OF SHARPS INJURIES

A. OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

Occupational exposure to bloodborne pathogens is a significant hazard faced by healthcare workers and a pressing concern for their employers. Bloodborne pathogens that cause many serious and potentially deadly infections include, but are not limited to, human immunodeficiency virus (HIV) hepatitis B virus (HBV), and hepatitis C virus (HCV).

Despite use of universal precautions and the introduction of needle safety products, healthcare workers are one of the few occupational groups who remain at risk for infection from bloodborne pathogens (Sepkowitz, 1996). Over 1400 healthcare worker infections to Hepatitis B occurred in 1993 due to needlestick injuries (Centers for Disease Control and Prevention (CDC), 1997a). As of December 1999, 56 health care workers in the U.S. have confirmed, occupationally transmitted HIV infection (CDC, 1999). Recent studies have reiterated that occupational exposure to bloodborne pathogens is a major concern among healthcare workers in many different settings (Aiken, Sloane, Klocinski, 1997; Folin & Nordstrom, 1997; Fraser & Powderly, 1995; Gershon & Karkashian et al., 1999; Haiduven, Askari, Gross, & Fisher, 1997; Lum, & Mason et al., 1997; Lymer, Schutz, & Isaksson, 1997).

It is estimated that health care workers in California sustain approximately 96,000 needlestick injuries per year (DIR, 1999). There are over 700,000 healthcare workers in California (EDD, 1999). Many of these workers are at risk for occupational exposure to life-threatening bloodborne pathogens including HIV, HBV, and HCV. The greatest risk for the transmission of bloodborne pathogens is associated with skin-puncturing injuries involving hollow-bore needles and other sharp medical devices contaminated with patient blood (Hibberd, 1995). These injuries occur when healthcare workers use, disassemble, or dispose of the needle device or other medical sharp. Housekeeping and laundry workers are also at risk for injury from improperly disposed contaminated sharps concealed in linen and waste.

Between 600,000 and 800,000 needlestick injuries occur in the U.S. each year (EPINet, 1999; Henry & Campbell, 1995). Underreporting of needlestick injuries, however, is estimated to be between 30-96 percent, suggesting that the actual rate of such injuries is much higher (Burke and Madan, 1997; Hamory, 1983; Mercier, 1995; OSHA, 1997). It has been estimated that, in an average hospital, workers sustain approximately 30 needlestick injuries per 100 beds per year (EPINet, 1999).

The EPINet data-sharing network reported that, in 1996, 3,167 needlestick and

sharps-related injuries, excluding those sustained before needle use, occurred among 65 participating hospitals with an average daily census of 10,720. Nurses (registered nurses and licensed practical nurses) reported the highest number (450 or 46 percent) of sharps injuries, followed by physicians, including attending/staff and interns, residents, and fellows, (475 or 15 percent), and other workers (278 or 9 percent). Most injuries occurred in patient rooms (34 percent), and the operating rooms (23 percent). The injured worker was the original user of the sharp item in 55 percent of the cases, indicating that almost half were injured by needles not initially in their control. Procedures responsible for most of the injuries were: giving intramuscular or subcutaneous injections (492), phlebotomy (421), and suturing (398) (International Health Care Worker Safety Center, 1999b; Jagger, 1997).

HIV Cases

The Centers for Disease Control and Prevention (CDC, 1999) reports that 56 documented and 136 possible cases of work-related HIV infection occurred between 1985 and December 1999. Most of these cases involved nurses and laboratory workers; sharps-related injuries were associated with 89 percent of the documented transmissions.

The estimated risk of infection after a skin-puncturing exposure to HIV-infected blood has been estimated to be between 0.3 percent and 0.4 percent and from a mucous membrane exposure is 0.09 percent (Chamberland, Ciesielski, Howard, Fry, & Bell, 1995; Rosenberg, Becker, & Cone, 1989). However, this risk may be reduced with the use of post-exposure prophylaxis (CDC, 1998; CDC, 1991, Gerberding, 1995; Hanrahan & Reutter 1997). There is, however, no currently available vaccine or effective treatment for preventing or curing HIV.

A study to assess the risk factors associated with acquiring HIV after exposure to HIV infected blood was conducted by the CDC, in collaboration with French and British public health authorities (CDC, 1995). This study showed that risk factors for HIV transmission include: deep injury, a device visibly contaminated with the source patient's blood, procedures involving a needle placed directly in the source patient's vein or artery, death of the source patient within 60 days of exposure, and a high HIV level in the source patient's blood. Identification of these risk factors suggests that the risk for HIV infection exceeds 0.3 percent after skin-puncturing exposures involving a larger volume of blood and/or higher HIV viral level (CDC, 1995).

HBV Cases

In 1995, approximately 800 healthcare workers became infected with HBV, a 95 percent decline since 1983. This is likely due in large part to availability of vaccine to prevent HBV among high-risk groups, including healthcare workers (CDC, unpublished data, cited in NIOSH, 1999). The risk of acquiring HBV infection from a needlestick

with a contaminated needle is between 6 percent and 30 percent. Approximately 5-10 percent of infected healthcare workers become chronically infected and then are at risk for developing cirrhosis and cancer (Aiken et. al., 1997; CDC, 1997a).

HCV Cases

The number of healthcare workers who have acquired occupational HCV infection is unknown. However, of the total number of annual cases, 2-4 percent occurs in healthcare workers who have been exposed to blood in the workplace (CDC, 1998; NIOSH, 1999). Estimates of the risk of HCV transmission after a skin-puncturing exposure average 1.8 percent, but may be as high as 7 percent (NIOSH, 1999). However, there is no immunization currently available for HCV. Moreover, symptoms of HCV often do not emerge for 20-30 years after viral transmission occurs; thus the disease is often unknowingly spread for 20 years or more before it is diagnosed. As many as 85 percent of those infected with HCV develop chronic liver infection. Those with this condition are at risk for cirrhosis and live cancer (CDC, 1997b). Treatment for these conditions may require a liver transplant.

B. COSTS OF SHARPS INJURIES

The consequences of occupational diseases transmitted from sharps injuries are many and may include healthcare worker death and severe disability from HIV, HBV or HCV infection. These diseases may also be transmitted to family members. Treatment costs can be prohibitive and are ultimately borne by healthcare institutions, workers' compensation insurers, injured workers and their families, and public resources. Even when an infection is not transmitted, the emotional burden on injured workers and their families is often severe (NIOSH, 1999). Healthcare workers who sustain a blood exposure must wait for results of repeated blood testing over a period of at least six months before knowing with certainty that infection has not occurred.

The average cost of needlestick injuries per individual hospital is \$24,840 a year (EPINet, 1999). The direct estimated cost of post-exposure follow up (lab tests, treatment, service, other) for skin-puncturing injuries (June 1, 1995-May 31, 1997) was from \$539 to \$672 (Jagger, Bentley, & Julliet, 1998). The Veterans Administration (1994) estimated that costs for fiscal year 94 ranged from \$205 (source negative for all bloodborne markers) to \$2,032 (source positive for all bloodborne markers). These costs included lab fees, immunization/medication costs, supplies, and personnel follow-up time.

HIV Treatment Costs

The cost of providing medical care to a patient infected with HIV averaged \$20,000 per patient per year for adults seen at least once every 6 months in 1996 (Bozzette et al., 1998). Lifetime costs for HIV medical care exceeds \$195,000. (Holtgrave, 1997).

Indirect lifetime costs are estimated at \$1,000,000 (Kent, 1998).

HBV Treatment Costs

The cost of treating a patient infected with HBV with a combination therapy of interferon and ribavirin can cost \$10,000 (Wong, 1999). The cost of a liver transplant and first year treatment averages \$314,500. Treatment with immunosuppressant drugs, to prevent organ rejection, cost \$29,100 per year. (Hauboldt, 1996).

HCV Treatment Costs

The costs for treatment of HCV with combination therapy are the same as those for HBV. A liver transplant and first year costs are the same as for HBV. Treatment with immunosuppressant drugs to prevent organ rejection, as with HBV, cost \$29,100.00 per year (Hauboldt, F., 1996). A single HCV case has incurred over \$600,000 in costs (Ball, 1998).

C. SAFETY-ENHANCED MEDICAL DEVICES

The use of needleless systems and devices with engineered sharps protection are the most effective ways of reducing sharps-related injuries and bloodborne pathogens exposure. One researcher has documented that shielded safety syringes reduced the rate of needlesticks from 14/100,000 inventory units to 2/100,000 in a study at three medical centers (Younger, 1992). Following a report that the highest rates of injury were associated with devices requiring disassembly after use, there has been a dramatic shift from attempts to modify behavior of healthcare workers, toward developing and introducing engineering controls and/or substitution to control sharps injuries (Jagger, Hunt, Brand-Elnaggar, & Pearson, 1988).

The optimal solution is to reduce the use of needles by using alternative methods for performing medical procedures whenever possible, and to effectively eliminate needles from medical devices. For instruments that require needles, the best approach is to design devices that allow the needle to remain shielded during and after use. The worker's hands should remain behind the needle at all times to prevent injury.

Several additional studies have shown that using safety-enhanced needle devices can reduce the risk of injury among healthcare workers. For example:

- Blunt suture needles reduced needlesticks during gynecologic surgery by 86 percent (CDC, 1997c);
- Safer blood-drawing needles reduced needlesticks by 27-76 percent, without reducing the quality of patient care, in a six-hospital study coordinated by the CDC (CDC, 1997d); and

- Needleless intravenous (IV) connection systems have been shown to reduce reported puncture injuries by 54 percent (Lawrence & Delclos et. al., 1997).

Examples of safer needle devices were cited in a recent review by Federal OSHA (OSHA, 1997). These include: needleless IV connectors, shielded needles (that allow a needle in a plastic sleeve to be used as a connector to an IV line), needle guards (providing a sleeve or sheath to cover a needle following use), and retractable needles (providing for needle retraction inside the syringe following use).

While some data indicate that there is no single solution for preventing needlestick injuries (ECRI, 1991), the greatest impact in reducing sharps injuries in healthcare workers continues to be achieved by innovative technology-based approaches to prevention (Becker, Gerberding, & Cone, 1989; Bonner, 1999; NIOSH, 1999).

Evaluation of Studies on Safety-Enhanced Medical Devices

Between 1993 and 1995, the CDC conducted two studies evaluating safety devices for preventing skin-puncturing injuries to healthcare workers (CDC, 1997c, 1997d). Both studies were restricted to a comparison of safety devices to conventional devices, not with other safety devices. The findings in both reports suggest that safety devices can be an effective component in a needlestick prevention program.

a) Phlebotomy

The first study (CDC, 1997d) evaluated safety devices for preventing skin-puncturing injuries (PIs) during phlebotomy procedures in six hospitals in the United States. Phlebotomy, one of the most commonly performed medical procedures, has been associated with 13-62 percent of injuries reported to hospital occupational health services. The study evaluated two types of devices (total of 3 products) including one winged steel needle and two vacuum-tube blood-collection devices. The findings indicate that the use of safety devices for phlebotomy can reduce the risk for occupational PIs among healthcare workers while having minimal clinically apparent effects on patient care. Specifically, there was a 66 percent and 76 percent reduction in phlebotomy-related PIs associated with use of each of the vacuum tube blood collection devices and a 23 percent reduction in PIs associated with use of the winged steel needle.

b) Surgical Procedures

The second study (CDC, 1997c) evaluated safety devices for preventing PIs during surgical procedures, which have been reported during 1-15 percent of surgical proce-

dures, most occurring during suturing. This study was conducted in three teaching hospitals in New York City to evaluate a safety device, the blunt suture needle, as a potential replacement for conventional curved needles in gynecologic surgery. The findings indicate that use of blunt suture needles effectively reduced suture related PIs during gynecologic surgical procedures, with minimal clinically apparent adverse effects on patient care and a general acceptance by gynecologic surgeons in these three hospitals. In particular, the increase in use of blunt suture needles was associated with a decrease in PIs, from curved suture needles, from 5.9 PIs per 100 procedures in 1993 to 1.1 PIs per 100 procedures in 1994. This study determined that the estimated odds of a PI with a curved suture needle were reduced by 87 percent when 50 percent of the suture needles used during a procedure were blunt.

Effectiveness of devices, device-specific injury rates, work practices, and environmental factors have been addressed in the literature (CDC, 1997c, 1997d; Chiarello, 1995; Haiduven, Phillips, Clemons, & Stevens, 1995; Haiduven et al., 1997; Hanrahan et al., 1997; Ippolito, & Puro, et al., 1994; Jagger, et al., 1988; Jagger, Hunt, & Pearson, 1990; Lawrence et al., 1997; McCormick, Meisch, Ircink, & Maki, 1991; Patel & Tignor, 1997; Rice, McCabe, & McManus, 1996). More than 1,000 patents have been granted since 1984 for needlestick prevention devices (Jagger, 1996). Many of these products have unique designs, but are difficult to use in health care situations.

Recent Implementation of Safety-Enhanced Medical Devices by Healthcare Institutions

Healthcare institutions have only recently begun to implement newer safety-enhanced needle devices as a method of prevention. This implementation process was accelerated by the revision of the Cal/OSHA Bloodborne Pathogens Standard. The Bloodborne Pathogens Standard (Title 8 California Code of Regulations, Section 5193), revised in July 1999, now specifically requires the use of needleless systems and needles with engineered sharps injury protection when available and medically appropriate.

“The California List of Needleless Systems and Needles with Engineered Sharps Injury Protection (List)” has been developed in accordance with California Labor Code Section 144.7 by the Sharps Program in conjunction with Cal/OSHA. The List was developed to assist employers in identifying safer devices and their manufacturers. The List provides names of devices available for purchase in California that meet the definition of needleless system or needles with engineered sharps injury protection, as defined in the newly revised Bloodborne Pathogens Standard. Please see the California List of Needleless Systems and Needles with Engineered Sharps Injury Protection (<http://www.dhs.ca.gov/ohb>) to view the 60 plus devices that may be substituted for conventional needles (**Appendix 1**).

A Device Manufacturer’s Estimate of Annual Savings in California Medical

Costs

The "Initial Statement of Reasons," prepared by Cal/OSHA for the Occupational Safety and Health Standards Board, for the revised Bloodborne Pathogens Standard (attached as Sub-Appendix C of Appendix 10) stated that: One device manufacturer estimated annual savings of \$444 million in California medical costs would result. The estimate included savings of \$228 million per year by eliminating new cases of HIV and savings of \$216 million resulting from the reduction in hepatitis due to eliminating the reuse of syringes. The cost estimate for the conversion to new safety devices was \$124 million. This would result in net savings to California of \$320 million. (DIR, 1999).

III. THE CALIFORNIA SHARPS INJURY CONTROL PROGRAM

In 1997, the SHARPS Program initiated a statewide voluntary pilot surveillance program as directed by SB 2005. In 1999, the SHARPS Program inaugurated the List of Needleless Systems and Needles with Engineered Sharps Injury Protection as mandated by AB 1208. Necessitated by the needs and interests of healthcare agencies, the SHARPS Program has also completed a series of research, education and outreach activities. This section will highlight the accomplishments of the SHARPS Program, present preliminary results of SHARPS surveillance efforts, and provide a summary of education and outreach activities.

A. SUMMARY OF PROGRAM ACCOMPLISHMENTS

The following are the major accomplishments of the Sharps Injury Control Program:

- Developed a model occupational Sharps Injury Registry, demonstrating the feasibility of establishing an ongoing surveillance system;
- Developed a model Sharps Injury Log;
- Analyzed sample sharps injury data obtained from Doctor's First Reports of Occupational Injury or Illness;
- Conducted a statewide survey of licensed hospitals, home health agencies, and skilled nursing facilities to determine reporting methods and safety enhanced device usage;
- Developed a continually-updated List of Needleless Systems and Safety-Enhanced Needle Devices (This is an ongoing unfunded mandate of AB1208);
- Developed a Device Evaluation Resource guide;
- Modified a checklist to assist institutions in monitoring their level of compliance with the Cal/OSHA Bloodborne Pathogens Standard; and
- Educated infection control practitioners, occupational safety and health professionals, and other healthcare providers about sharps injury prevention and the revised Cal/OSHA Bloodborne Pathogens Standard.

B. STAKEHOLDER WORKING GROUP

The SHARPS Program initiated a series of stakeholder meetings, beginning in December 1996. These meetings were designed to serve as a venue for those affected by SB 2005 to provide input on SHARPS Program implementation decisions, give updates on developments from the field, discuss areas of concern, and work towards common goals. Stakeholders participated in increasing numbers. By October 1998, the SHARPS Program conducted meetings by video teleconference to accommodate stakeholders in both northern and southern California, with an additional link to CDC/NIOSH in Atlanta.

Currently there are over 125 stakeholders who contribute to the SHARPS Program through their feedback on current projects, suggestions for future activities, and commitment to reducing the incidence of needlesticks in California. The stakeholders for the SHARPS program meet several times a year.

Topics addressed at SHARPS stakeholder meetings have included:

- Evaluating and selecting safe and effective needle devices;
- Developing the mandated Sharps Injury Log;
- Discussing needlestick surveillance mechanisms and software;
- Presentation of studies and surveys;
- California Doctor's First Reports of Sharps Injuries;
- Intervention Study of Sharps Disposal Container Placement (at SFGH);
- Home Healthcare Survey;
- Self-assessment Guidelines for Large Quantity Medical Waste Generators;
- Discussing the San Francisco Chronicle series titled "Deadly Needles;"
- Legislative updates on AB 1208;
- Regulatory updates on the Cal/OSHA Bloodborne Pathogens Standard;
- Developing the List of Needleless Devices and Needles With Engineered Sharps Injury Protection; and
- Demonstrations of new devices by manufacturers.

Stakeholders participating in SHARPS stakeholder meetings represent a broad spectrum of those affected by SB 2005. Entities represented in the stakeholders group include: trade/industry associations (infection control, medical, hospital, nursing home, home health, and funeral services); health care institutions (public and private acute care hospitals, university teaching hospitals, public health clinics/immunization programs); labor organizations (state, regional, and local healthcare worker unions, and the state labor federation); medical device representatives (manufacturers, inventors, and legal counsels); educational institutions (schools of medicine, dentistry and nursing; university-based labor health and safety programs, a medical device research project; and students); and government (county public

health agencies, state departments of health, industrial relations, corrections, and environmental protection, and federal agencies for worker safety and health, and medical device safety).

C. SHARPS INJURY REGISTRY RESULTS

California became the first state in the U.S. to develop a Sharps Injury Registry (Registry). Although participation is voluntary, to date 199 healthcare institutions have provided injury data to the Registry. A total of 1,940 reports of needlesticks and other sharps injury have been received regarding injuries that occurred during the two-year period between January 1, 1998 and December 31, 1999. In addition, 243 other facilities reported that they had no sharps related injuries during this time.

These reports provide a useful basis for evaluating the effectiveness of control efforts prior to the revision of the Cal/OSHA Bloodborne Pathogens Standard. The Registry also provides a basis for evaluating the effectiveness of the revised standard. The Registry encourages institutions to track their injuries in a standardized format that facilitates compliance with the data elements required by the Bloodborne Pathogens Standard. Facilities are required by the Bloodborne Pathogens Standard to review, analyze and interpret their own data on a periodic basis. Those facilities that have volunteered to provide injury data submit their reports to the Registry on the standardized Sharps Injury Log or using the format most convenient to them. The Registry provides a benchmark against which facilities can evaluate their efforts. Continued maintenance of the Registry is important to the many local facilities that have limited experience aggregating and analyzing this type of injury data. The Sharps Injury Control Program clearly demonstrated the feasibility of establishing an ongoing surveillance system. In fact, the Registry developed by the SHARPS Program is being used as a model by other states that are enacting or considering enacting similar legislation. The Registry was used as a model for the data elements required under the recordkeeping provisions of the new Federal Needlestick Safety and Prevention Act signed into law by President Clinton on November 6, 2000.

1. Development of the Sharps Injury Log

The first step in establishing the Sharps Injury Registry was the development of a scannable sample Sharps Injury Log designed to be a cost-efficient data retrieval mechanism. The Sharps Injury Log (Sharps Log) contains all the data elements needed by an institution to comply with new recordkeeping requirements of the revised Cal/OSHA Bloodborne Pathogens Standard (see **Appendix 2** for the Sharps Log). The Sharps Log allows for institutions to use a facility-assigned injury identification number to protect worker confidentiality. The sample Sharps Injury Log was made available on the Internet (<http://www.dhs.ca.gov/ohb>), and by facsimile or mail upon request.

2. Sharps Injury Registry

Methods

The SHARPS Program requested sharps injury data from 2,790 California hospitals, home health agencies, and skilled nursing facilities in a January 1999 mailing. Facilities were sent a cover letter soliciting their voluntary participation in the Sharps Injury Registry. They were also given a three-page survey on device use and data collection methods, a sample Sharps Log, a SHARPS Program brochure, and notice of expected revisions to the Cal/OSHA Bloodborne Pathogens Standard.

The SHARPS Program accepted data in all formats, including handwritten reports, in addition to the Sharps Logs. Data provided in non-standard formats were coded as fully as possible by SHARPS staff. Standardizing data to the Sharps Log allowed us to maximize the utility of the data received. The data on injuries were coded by trained coders, standardized, and entered into a database, with all obvious erroneous data removed. Data, once entered, were subjected to a complete verification process, and initial frequencies were checked for outliers.

Facility Responses

The SHARPS Program has received 1,940 voluntary injury reports from 199 institutions as of January 31, 2000. Of the 1,940 injuries reported, 1780 (91.8 percent) of them were reported by hospitals. A total of 1297 (66.9 percent) of the cases were reported on non-standard forms, which necessitated extensive coding by SHARPS staff. Much of the information required to properly evaluate the injuries was missing, which made analysis even more difficult. For example, only 69.3 percent of the forms identified the injured employee's job classification, a key variable in injury analysis.

Employee Injuries

Of the reports where job classification was indicated, nurses sustained the highest number of injuries (658 or 49 percent), followed by physicians (139 or 10.3 percent), phlebotomists (110 or 8.2 percent), technologists (80 or 6.0 percent), and nursing assistants/home health aides or orderlies (78 or 5.8 percent).

Circumstances of Injuries

Of those reports where body part injured was reported, the finger/thumb was the most often reported body part injured (799 or 81.4 percent). A total of 290 (21.9 percent) of the injuries were associated with giving injections while another 261 (19.7 percent) were association with drawing venous blood (numbers include non-original users). There were 399 (29.7 percent) reported injuries during device use and another 312 (23.2 percent) after use but before disposal of the sharps device. The injuries reported where the injured employee was not the original user of the sharp included 102 (20.6

percent) involving equipment/instrument cleaning, 116 (23.5 percent) assisting with a procedure, and 59 (11.9 percent) contact with trash. Patient rooms (361 or 24.8 percent) and operating rooms (272 or 18.7 percent) were the most frequent injury locations reported.

Devices Involved in Injuries

Seventy-eight percent of the facilities were able to describe the type of device involved in the injury; however, only 24.2 percent knew the brand and only 17.7 percent knew the model. For all of the facilities where type of device causing injury could be determined, 490 (29.8 percent) of injuries were caused by disposable syringes, 264 (16.1 percent) by a needle of undetermined type, 133 (8.1 percent) by intravenous (IV) catheter stylets, 133 (8.1 percent) by suture needles, and 115 (7.0 percent) by winged steel needle used for drawing blood or IV access.

Injured Employees' Opinions About Injury Prevention

When asked whether an injured employee had an opinion whether or not an engineered sharps injury protective device could or would have prevented the injury, 327 (66.6 percent) of those responding indicated "yes". However, only 191 respondents explained their opinions. The specific opinion of 119 (62.3 percent of those who reported specific opinions) was that an engineered sharps device could or would have prevented the injury. In 14 cases (7.3 percent), a safety device was used but the user suggested that design modifications were needed. In 15 cases (7.9 percent), users responded that a safety device could not have prevented the injury. In 9 cases (4.7 percent), a safety device was in stock but not used. A safety device was not available in 9 cases (4.7 percent). In 9 cases (4.7 percent), the device had a safety feature but it was not yet activated at the time of the injury. In 5 additional cases, (2.6 percent), a safety device was believed likely to hinder the procedure.

Other controls that injured employees thought could have prevented the injury included human factors (117 or 37.6 percent); proper sharps disposal (62 or 19.9 percent); improved sharps disposal container design, placement or timely maintenance (25 or 8.0 percent); revised policies or procedures (22 or 7.1 percent); improved staffing and/or training (18 or 5.8 percent); or avoidance of recapping (16 or 5.1 percent).

For a summary of Registry injury data, please see **Tables 1-17**.

D. DOCTOR'S FIRST REPORTS

As part of the pilot surveillance system, SHARPS staff reviewed Doctor's First Reports of Occupational Injury or Illness (DFRs). All occupational injuries that result in a medical examination, where medical treatment is provided or offered, are required to be reported on DFRs and submitted to the Department of Industrial Relations, Division of

Labor Statistics and Research. Some healthcare institutions, however, do not report needlestick injuries on DFRs. Geographic variation in reporting and batching of reports by insurance companies seem to occur, possibly skewing the results. Despite known reporting difficulties, DFRs are one indicator of the number of needlesticks in California, and warrant analysis.

Methods

All DFRs for a period of four weeks in 1997 and two weeks in 1998 were reviewed. Those with key words indicating a sharps-related injury were selected. All non-duplicate cases involving a needlestick or lancet injury were included in the analysis. Each case was classified according to age group, gender, occupation, industry, activity causing injury, type of device (rarely listed), and type of treatment or post-exposure prophylaxis offered. Recognizing the problems inherent in this system, needlesticks reported during the six weeks were analyzed and the following results were reported:

Results

- **231 needlestick and other sharps injuries were identified;**
- The median age group was 30-39 years, and the majority of those injured were women (64 percent);
- Occupations with the most needlesticks: nurses (31 percent), medical assistants/dental technicians (12 percent), and emergency responders (8 percent);
- Industries with the most needlesticks: hospitals (42 percent), other medical (17 percent), fire/police/prison (6 percent), and schools and colleges (5 percent);
- The event most often associated with injury: phlebotomy (15 percent), disposal of used sharps (14 percent), and IV insertion, injection and housekeeping activities (5 percent each); and
- Most frequently reported devices: needles (76 percent), IV stylets (5 percent), suture needles (4 percent), and lancets (3 percent), though type and brand of device was rarely identified.

DFRs Appear to Understate Sharps Injuries

As healthcare workers may not report an injury and an institution may fail to use DFRs, both can contribute to a considerable underestimate of the true number of sharps-related injuries using DFRs alone. An estimate for the actual number of injuries in California could be based on national estimates of 600,000 to 800,000 needlestick injuries in the U.S. each year (EPINet, 1999; Henry & Cambell, 1995; NIOSH, 1999). Assuming that California has approximately 12 percent of the U.S. population, and therefore 12 percent of all U.S. injuries, we would expect to see between 72,000 and 96,000 needlestick injuries in California each year. However, only 60 sharps injuries per week are reported on DFRs, which is equivalent to only 3,000 sharps injuries per year. The requirement for electronic reporting of DFRs, expected to go into effect in the near future, will likely improve the accessibility and utility of this data source.

E. SURVEY OF HEALTHCARE FACILITIES

The SHARPS Program conducted a voluntary statewide survey of all licensed hospitals, home health agencies, and skilled nursing facilities regarding their sharps-injury surveillance methods, use of safety-enhanced devices, and need for educational materials and/or technical assistance. Institutions were asked to identify which department collected sharps data, how it was collected, and where it was kept. They were also asked to identify the types of sharps injury prevention devices used, whether or not they were testing safety devices, and whether or not they were interested in participating in SHARPS Program activities. Institutions were also invited to send sharps injury data to the Sharps Injury Registry (see Sharps Injury Control Program Facility Survey, **Appendix 3**).

Methods

To conduct this survey, a list of institutions was obtained from the DHS, Division of Licensing and Certification (L & C). In January 1999, the initial survey was mailed, followed by a reminder postcard and second mailing to further encourage participation. During this period, L & C updated their list of institutions and a third mailing was made to those institutions newly added to this list.

Survey Response

After correcting for duplication, incorrect addresses, and changes in ownership, the final number of eligible institutions was 2,654. Of these, 1,273 (47.9 percent) responded to the survey by August 15, 1999. Please refer to **Tables 18-29**, for a summary of the results. Fifty-six percent of hospitals, 51 percent of skilled nursing facilities, and 38 percent of home health agencies responded to the survey, however only 18.3 percent of the responders enclosed sharps-related injury data. Most institutions record data in written format, with a small percentage using both written and electronic formats.

Recording Injuries

Sharps-related injuries are recorded in multiple places and in various ways by individual institutions. Seventy percent of hospitals, 43 percent of skilled nursing facilities, and 41 percent of home health agencies record sharps injuries on the OSHA Log 200. Only 66 percent of hospitals, 37 percent of home health agencies, and 33 percent of skilled nursing facilities reportedly record sharps injuries on a Sharps Injury Log, although SB 2005 mandated this. Institutions also varied according to which department keeps records of sharps injuries. Overall, 49 percent reported that the primary office responsible for keeping these records was the infection control office, followed by employee health (39 percent).

Approximately 90 percent stated they record a description of the injury, job title, date and time of injury, task performed, location where the injury occurred, body part injured, and type of device involved in the incident. Approximately 66 percent stated they record the brand of the device and the manufacturer. Although many institutions stated that they record the type of device, this is not consistent with information reported to the Registry. It appears that identification of type and brand of device is difficult to determine by persons reporting the injuries and those recording the event.

Safety Device Use and Evaluation

More than 70 percent of all institutions stated that they use some type of safety-enhanced needle or needleless injection system. However 26 percent reported using no type of safety-enhanced devices. Forty-eight percent reported that they did not yet use safety blood collection devices; 29 percent did not use needleless IV systems and 25 percent did not use safety lancets. Eighty-three percent of hospitals, but only 27 percent of home health agencies and 27 percent of skilled nursing facilities have evaluated safety-enhanced sharps devices.

Information and Technical Assistance Needs

Eighty-five percent of responding institutions requested additional educational material from the Sharps Injury Control Program on topics such as sharps injury surveillance, bloodborne pathogens, and device selection and evaluation.

F. MANUFACTURERS' SURVEY

AB 1208 required Cal/OSHA and the SHARPS Program to jointly compile a List of Needleless Systems and Needles with Engineered Sharps Injury Protection (List). The categorization of new technologies was developed jointly by DHS and DIR staff, based on the types of devices submitted for potential listing. All devices listed are 'needleless devices' that replace existing needle systems, or have 'engineered sharps injury protection' built into the needle device itself.

Purpose of the List

The List is available to assist employers in complying with the revised Cal/OSHA Bloodborne Pathogens Standard. Its purpose is to help users assess their needs, evaluate devices, locate manufacturers of safety-enhanced devices, and obtain devices more easily. Maintaining the List is an ongoing process that requires frequent updating as new devices become available and new manufacturers are identified. The List is available on the SHARPS Program web site and also in hard copy, distributed by Cal/OSHA and the SHARPS Program.

Method Used to Develop and Disseminate the List

To develop the List, the SHARPS Program identified manufacturers of needleless systems and safety-enhanced needle devices from diverse sources including the U.S. Food and Drug Administration and the U.S. Department of Veterans Affairs. A survey was mailed to over 100 medical device manufacturers in the United States. Information was requested regarding device descriptions, specifications, safety features, evaluation studies, and suggested retail price. To date, device information has been obtained for approximately 80 needleless systems and safety-enhanced needle devices, of which over 60 met the Cal/OSHA criteria.

Data on devices are supplied by manufacturers and reviewed by SHARPS Program staff, in collaboration with Training for Development of Innovative Control Technology (TDICT) and Cal/OSHA. The group ascertains that each device submitted meets the criteria of a “needleless system” or has “engineered sharps injury protection” as defined in the Cal/OSHA Bloodborne Pathogens Standard. No further evaluation of the devices listed is conducted. References are provided to publish research on the efficacy of the device in prevention of injuries, although there are currently no published direct comparisons of safety devices to determine their comparative effectiveness in preventing sharps-related injury. The List is posted on the SHARPS Program web site (<http://www.dhs.ca.gov/ohb>) or is available upon request. (See **Appendix 1** for the most recent version of the List and **Appendix 4** for the Survey of Manufacturers Products Questionnaire.)

G. DEVICE EVALUATION RESOURCES

The revised Cal/OSHA Bloodborne Pathogens Standard requires healthcare employers to create a process to identify and evaluate safety-enhanced devices. The SHARPS Program was also mandated by SB 2005, to provide information and references to articles regarding methods of evaluating safety-enhanced medical devices to interested parties. The SHARPS Program developed a Device Evaluation Resource Guide (Guide) to assist institutions in their device evaluation efforts. The Guide contains current information on contacting organizations knowledgeable about device evaluation and finding relevant published articles. The Guide is available both on the SHARPS Program web site (<http://www.dhs.ca.gov/ohb>) and in hard copy. (See **Appendix 5** for a copy of the Guide.)

H. COMPLIANCE CHECKLIST

A Bloodborne Pathogens Assessment Checklist (Checklist), previously developed by Kaiser Permanent staff, was modified by a SHARPS program staff member to assist institutions in complying with the revised Cal/OSHA Bloodborne Pathogens Standard. The Checklist is divided into three sections: “Records and Documents,” “Inspections and Tours,” and “Interviews.”

The records and documents section is used to assess the required Exposure Control Plan, training, Hepatitis B vaccination programs, and recordkeeping activities. Recordkeeping refers to post-exposure documentation, including maintenance of a Sharps Injury Log and OSHA Log 200 entries. The inspection and tours section assists in assessing infection control program activities, exposure risk determination, work practices, protective clothing and equipment, and safety device use. The interview section assists the surveyor in assessing knowledge of bloodborne pathogens and approaches to exposure prevention and control. The results of the assessment demonstrate to employers how effectively they comply or deviate from regulatory requirements, utilize infection control practices, and address risks to employees. (See **Appendix 6** for a copy of the Checklist.)

I. EDUCATIONAL ACTIVITIES AND MATERIALS

Education/Outreach and Technical Assistance

The SHARPS Program has been in constant demand as an objective source of information on bloodborne pathogens and preventing sharps injuries. SHARPS staff were expert speakers at conferences and workshops across California, the U.S. and at international conferences. They also provided technical assistance to over 1,000 institutions and to infection control and other healthcare health and safety personnel throughout California. Both conference attendees and telephone callers requested information on how to report sharps injuries, how to select and evaluate safety devices, how to prevent injuries, and what to do immediately following a blood or other bodily fluid exposure. The SHARPS Program has also provided information and technical assistance to protect the public and employees at risk of exposure to blood in non-healthcare industries (e.g., park services, food processing, garment and manufacturing).

Educational Materials

The SHARPS Program has developed educational materials to assist both healthcare employers and workers on a variety of topics. Previously mentioned educational products include the SHARPS Program Brochure, Sharps Injury Log, and the Bloodborne Pathogens Assessment Checklist. In addition, SHARPS staff co-authored a Hepatitis C Fact Sheet (**Appendix 7**). The SHARPS Program developed a web site to disseminate educational materials: <http://www.dhs.ca.gov/ohb>.

J. SHARPS PROGRAM COLLABORATIONS

Training for Development of Innovative Control Technology

One prominent research group and collaborator of the SHARPS Program is the Training for Development of Innovative Control Technology (TDICT) project. The TDICT project is a CDC-funded program of the Trauma Foundation and is affiliated with the San Francisco General Hospital and the San Francisco Center for Injury Prevention and Research. Started in 1990, TDICT has brought together healthcare workers, product design engineers and industrial hygienists that are dedicated to preventing bloodborne pathogens through better design and evaluation of medical devices and equipment.

TDICT developed a conceptual framework for categorizing new technologies to reduce needlestick injuries that has been adopted by DHS (Chiarello, 1995; TDICT, 1997). Devices may be categorized as follows:

- Passive (not requiring activation by user);
- Active (requiring user to activate the device);
- Integrated with the device (cannot be removed); and
- Accessory to the device (must be attached to the device at the point of use).

TDICT has collaborated with the SHARPS Program in several additional areas: providing speakers and trainers for workshops and conferences; providing assistance in development of the List of Needleless Systems and Needles with Engineered Sharps Injury Protection; designing display boxes for the SHARPS Program to use in educational efforts; working with SHARPS staff and CDC in evaluating NIOSH guidelines (NIOSH, 1998) regarding needlebox placement strategies; and, providing essential technical assistance to SHARPS Program activities. Prior research showed the effectiveness of engineering controls (e.g., placing needle disposal boxes closer to the bedside) in reducing one high-risk activity: needle recapping (Makofsky & Cone, 1993).

Medical Waste Management Program

The SHARPS Program collaborated with the DHS Environmental Management Branch, Medical Waste Management Program (MWMP) inspection staff regarding education and training in the use of the Sharps Log. MWMP has been involved in the implementation of SB 2005 through an educational approach from 1997 to the present. During this time, approximately 500 inspections per year, for the three-year

period, were made at large quantity waste generators. During these inspections, MWMP staff consulted with and informed site management, usually the Environmental Health and Safety managers, of the requirement of SB 2005 that facilities identify the types of devices that cause sharps injuries. A sample Sharps Injury Log was reviewed and distributed as necessary. Staff encouraged facilities to complete the forms when injuries occurred and to forward them to the SHARPS Program. This effort was directed to the 27 jurisdictions where the Department's MWMP acts as the local enforcement agency.

IV. DIRECTIONS FOR THE FUTURE

A. THE SHARPS INJURY CONTROL PROGRAM

As the SHARPS Program accomplishments indicate, DHS has made significant progress in the past 3 years toward addressing the issue of sharps injuries in healthcare institutions and preventing occupational exposures to bloodborne pathogens in California.

The SHARPS Program has served as a national model by conducting the first state-wide voluntary surveillance of sharps injuries; monitoring the development and implementation of innovative needlestick injury control strategies; developing a list of safety-enhanced medical devices; and providing consultations to healthcare institutions regarding cost-effective ways to reduce needle and other sharps-related injuries. However, much remains to be done to ensure that California healthcare workers do not continue to be exposed to HIV, HBV, and HCV from contaminated needles and other medical sharps.

The Sharps Injury Registry has the advantage in the revised Cal/OSHA Bloodborne Pathogens Standard, of being able to access all California Sharps Injury Log data. A more comprehensive Registry would better identify the highest risk procedures and devices. It would allow estimates of needlestick injury rates and device-related relative risks to be made and publicized. A statewide Sharps Injury Registry would be a cost-effective way to provide essential information to healthcare employers and workers.

Continuation of the SHARPS Program also assure availability of an updated List of Needleless Systems and Safety-Enhanced Needle Devices. Updating the list on a regular basis is necessary to ensure that healthcare providers and institutions have already access to information about the safest devices available.

Since seeking additional funding was encouraged by SB 2005, the SHARPS Program sought funding for both program continuation and expansion. A proposal to NIOSH to

evaluate the effectiveness of the Cal/OSHA Bloodborne Pathogens Standard was funded and is underway in collaboration with the University of California, San Francisco, School of Nursing. Since the original plan for the Sharps Program was for three years, the program experienced a gap in funding from June 30, 2001 - July 1, 2001. However, funding for at least one additional year was obtained beginning in July 1, 2001.

B. CONTINUED COLLABORATION WITH CAL/OSHA

DHS is mandated to educate employers, workers and health professionals about occupational health and safety (Health and Safety Code, Section 105175). Cal/OSHA is responsible for enforcing the recently revised Bloodborne Pathogens Standard (Title 8, California Code of Regulations, Section 5193) and providing free on-site industrial hygiene and safety engineering consultation services to employers who request them. DHS is mandated to coordinate with Cal/OSHA to avoid duplication of services (Health and Safety Code, Section 105180). The SHARPS Program was complementary to Cal/OSHA, rather than duplicative. Cal/OSHA and SHARPS collaborated closely on the Bloodborne Pathogens Standard revision to ensure that the Sharps Injury Log requirement provided adequate data fields for an effective ongoing Sharps Injury Registry.

AB1208 mandated that DHS, in conjunction with DIR, continue to produce an updated list of needleless systems or devices with engineered safety features. This was an unfunded mandate that was covered, during the existence of the Sharps Injury Control Program by staff of that program. As of June 30, 2000, this activity must be covered by redirecting work of existing staff of DHS and DIR. The workload for continuing this List is expected to increase as new technologies and devices are developed.

V. CONCLUSIONS AND RECOMMENDATIONS:

A. SHARPS PROGRAM REVIEW

Significant advances in prevention of needlestick injuries have occurred in the years since the previous Report to the Legislature on the Use of Safety-Enhanced Product Design for Medical Devices in California was submitted (HESIS, 1994). Media attention has focused on healthcare workers' illnesses and deaths from preventable needlesticks. As of July 1, 1999, all medical facilities in California are required to use safety-enhanced devices when such devices are available and are not medically contraindicated. These developments have generated a heightened demand for safer devices. Manufacturers have responded by introducing a wide array of innovative needleless and safety-enhanced needle devices into the marketplace. On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act (HR 5178 - Ballinger), establishing revisions to the Federal OSHA Bloodborne Pathogens stan-

dard similar to those adopted by California. In addition, recordkeeping requirements were established on a national basis that are modeled after the California standard. The DHS Sharps Injury Control Program served an important role in this unfolding process:

- SHARPS convened a group of stakeholders including representatives of healthcare institutions, healthcare worker unions, and device manufacturers who have met regularly over the past three years to guide the development of a prevention-oriented strategy for needlestick and sharps injury reduction;
- SHARPS developed a pilot Sharps Injury Registry that collected key information about the brand and type of devices involved in needlestick injuries, demonstrating the feasibility of establishing an ongoing surveillance system for needlestick injuries, and pointed the way for future prevention efforts;
- SHARPS developed and made readily available a List of Needleless Systems and Needles with Engineered Sharps Injury Protection for healthcare institutions and providers to consult when choosing devices to meet the revised Cal/OSHA Bloodborne Pathogens Standard requirements;
- SHARPS provided technical consultation to small and large employers, government agencies, union representatives and others regarding compliance with the new requirements in the Cal/OSHA Bloodborne Pathogens Standard for safety-enhanced devices;
- SHARPS Program findings led to a UCSF School of Nursing research study funded by NIOSH to determine the effectiveness of the revised Cal/OSHA Bloodborne Pathogens Standard through site visits to healthcare facilities to evaluate compliance with the new requirements;
- SHARPS has served as a model for implementing similar programs in other states and countries; and

CDC has set a goal of eliminating needlestick injuries by the year 2010. To meet this goal, it is important to track, analyze, and publicize injury trends. This will be difficult without an effective Sharps Injury Registry. Mandatory reporting of sharps injuries, similar to reporting of other adverse health events to health departments, combined with electronic reporting of data directly to the Registry, would likely increase Registry participation. Without an ongoing Registry, the opportunity to disseminate vital primary prevention information to healthcare institutions and providers will be lost. Another consequence could be continued use of conventional medical devices with their attendant hazards to healthcare workers. This could result in an adverse impact on disease prevention efforts in California.

B. RECOMMENDATIONS

1. Continue Innovative Improvements in Medical Device Design

The best method for preventing sharps injuries is to eliminate the use of needles or sharp components wherever feasible. Substantial progress has been made toward developing innovative design improvements in medical devices. These design improvements should continue. For instance, needleless air-jet injection systems have been developed for immunizations that can be substituted for conventional needle and syringe systems. Alternative medication delivery systems have been developed that have proven effective in some situations. Injection alternatives can deliver medication in liquid or powder aerosol form to mucous membranes of the mouth or nasal passages or by skin absorption from transdermal “patches.” An increasing number of medications such as insulin, interferon and various vaccines, are being tested for clinical effectiveness via alternative delivery mechanisms.

2. Increase Independent Evaluation Research on the Efficacy of New Safety-enhanced Devices

Currently there is a lack of independently funded research on safety-enhanced needle device efficacy. New generations of significantly re-engineered devices have been developed, but evaluation data directly comparing the effectiveness of devices in preventing sharps-related injuries are not currently available. The CDC and the Emergency Care Research Institute (ECRI) have conducted a limited number of studies. Although valuable, these studies have only evaluated a small number of devices.

A new mechanism needs to be developed to fund such research. One possible funding mechanism suggested by one of the representatives of Sharps Program stakeholders was a fee-based approach similar to that used by the Childhood Lead Poisoning Prevention Program. Fees could be collected from either device manufacturers or users. Although this fee would likely add a small cost to either the device or facility, it would be offset by provision of a greatly needed service. A fee-funded program could establish evaluation criteria and conduct facility-based evaluation and direct head-to-head comparison of the efficacy of new safety devices. Results of such evaluation studies could be efficiently tabulated and disseminated by an ongoing SHARPS Program.

3. Increase Availability and Affordability of Evaluation Research Materials

Information on the efficacy of devices must be accessible to increase usage of new safety-enhanced devices by healthcare facilities. Evaluation research materials such as those currently published by ECRI can be very expensive for smaller facilities. Subscriptions are \$2,495.00 per year. In addition, only four issues since 1991 have contained evaluations of needlestick prevention technology.

4. Expand and Update on a Regular Basis the List of Needleless Systems and Needles with Engineered Sharps Injury Protection

Currently, the List of Needleless Systems and Needles with Engineered Sharps Injury Protection is an invaluable resource for all device users. The List informs both device purchasers and users of the available devices that meet criteria established by Cal/OSHA. An up-to-date list provides a mechanism to easily identify new devices with which the purchaser or user may not be familiar. As there are a vast array of devices that differ in ease of use, safety attributes, and cost, it is beneficial for the purchaser and user to be informed about all available safety-enhanced devices.

5. Improve and Expand the Sharps Injury Registry Developed by the Sharps Injury Control Program

The availability of current data on device/injury ratios is essential to reducing bloodborne disease exposures to California healthcare workers. Areas in which the Sharps Injury Registry could be improved include clarifying data standards and developing electronic collection and reporting mechanisms (e.g., software and Internet data applications). Data standards improvements include development of a data dictionary to clearly outline how each data item is defined (e.g., job classification or procedure). A mechanism to improve injury reporting could include the development of electronic data collection and transfer to the Registry. This could be accomplished through the development of a software package or through Internet reporting. Many models exist for the timely transmission of data to health departments that use an electronic approach (e.g. cancer registration).

In addition to the Sharps Injury Registry, the Workers' Compensation Information System, which receives all DFRs will eventually be computerized. The electronic DFRs will include many data elements of the current paper version and facilitate access to needlestick injury data. As many sharps injuries are currently underreported to both the Registry and DIR, it would be possible to identify new cases or combine data from duplicate reports. This would allow for more accurate determination of the incidence of such injuries to better inform California's public health efforts.

C. CONCLUSIONS

The aim of primary prevention is to maintain health by eliminating precipitating causes of illness and injury. Public health is inherently concerned with justice and with fair and equitable distribution of resources in prevention programs. The aim of public health services should be to enlighten the affected communities about risks and assist them in gaining control over environmental and social conditions that influence health. Public health officials have an obligation to empower people in promoting injury and illness prevention (Last, 1992a; Last, 1992b). By promoting primary prevention strategies combined with effective tracking of injuries, the SHARPS Program, together with its stakeholders, has demonstrated the feasibility of establishing an ongoing needlestick injury surveillance system and provided direction and vision to those seeking to reduce injuries from contaminated sharps, helping to sustain the health and well being of California's caregivers.

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VI. INJURY REGISTRY DATA (TABLES 1-17)

**TABLE 1–SHARPS INJURIES REPORTED BY FACILITY TYPE
(N = 1940)**

Facility Type	Number of Injuries Reported	Percent of Reported Injuries
Hospitals (including some hospital-based Home Health Agencies)	1780	91.8
Skilled Nursing Facilities	74	3.8
Home Health Agencies	50	2.6
Other (e.g. surgery center, MD office, clinic)	36	1.9
Total	1940	100.0

TABLE 2–SHARPS INJURY RECORDING FORMAT (N = 1940)

Type of Log Used	All Cases N (percent)
Standard	480 (24.7)
Modified	153 (7.9)
Non-Standard	1297 (66.9)
From Facility Survey	10(<1)
Total	1940

TABLE 3—SHARPS INJURY BY JOB CLASSIFICATION (N = 1344)

Job Classification	Number of Injuries Reported	Percent of Reported Injuries
Nurse	658	49.0
MD/DO (including residents)	139	10.3
Phlebotomist/lab tech	110	8.2
Housekeeper/Laundry	91	6.8
Technologist	80	6.0
CNA/HHA/Orderly	78	5.8
OR/Surgical Tech	54	4.0
Respiratory Care Personnel	23	1.7
Student (including nursing, MD, EMT, and interns)	24	1.8
Medical assistants	22	1.6
Other *	65	4.8
Total	1344	100.0

*Other includes other healthcare professionals and paraprofessionals, administrative personnel, and central service employees.

TABLE 4–SHARPS INJURY BY GENDER (N = 696)

Gender	Number of Injuries Reported	Percent of Reported Injuries
Female	534	76.7
Male	162	23.3
Total	696	100.0

TABLE 5–AGE OF INJURED EMPLOYEE (N = 412)

Age in Years	All Facilities
Mean	38.48
Range	18 -72
Standard Deviation	10.27
Age group	Number (Percent of Reported Injuries)
<20	3 (<1)
20-29	96 (23.3)
30-39	124 (30.1)
40-49	131 (31.8)
50-59	47 (11.4)
60-69	10 (2.4)
70-79	1 (<1)

TABLE 6–SHARPS INJURY BY SHIFT WORKED (N = 821)

Shift Worked	Number of Injuries Reported	Percent of Injuries Reported
Day shift	464	56.5
Evening shift	227	27.6
Night shift	130	15.8
Total	821	100.0

TABLE 7–SHARPS INJURY BY BODY PART (N = 982)

Body Part Injured	Number of Injuries Reported	Percent of Injuries Reported
Finger	799	81.4
Hand	132	13.4
Arm	28	2.9
Leg	13	1.3
Other	10	1.0
Total	982	100.0

TABLE 8—SHARPS INJURY BY PROCEDURE FOR INTENDED USE OF SHARPS INSTRUMENT (N =1327)

Procedure	Number of Injuries Reported	Percent of Injuries Reported
Injection, through skin	290	21.9
Drawing venous blood	261	19.7
Suturing	140	10.6
Start or DC IV/set up heparin lock	136	10.2
Procedure/biopsy etc.	127	9.6
Manipulating IV or port, including injection into IV or port	105	7.9
Cutting	83	6.3
Finger/heelstick	53	4.0
Other task	52	3.9
Draw arterial blood	29	2.2
Accessing blood through a line or cord	18	1.4
Laboratory work	18	1.4
Accessing other body fluid	15	1.1
Total	1327	100.0

TABLE 9–SHARPS INJURY BY PROCEDURE WHEN EMPLOYEE NOT THE ORIGINAL USER OF THE SHARP OR WHEN MULTIPLE TASKS WERE BEING PERFORMED SIMULTANEOUSLY (N =494)

Procedure	Number of Injuries Reported	Percent of Injuries Reported
Equipment/instrument cleaning	102	20.6
Assisting with procedure	116	23.5
Contact with trash	59	11.9
Room cleaning	53	10.7
Sharps protruding from sharps container	37	7.5
Patient assistance/cleaning	30	6.1
Other	38	7.7
Removing sharps from inappropriate place (e.g., floor, keyboard, sink)	25	5.1
Manipulating sharps container/disposal	17	3.4
Discarding bio-hazard trash	10	2.0
Finger/heelstick	7	1.4
Total	494	100.0

TABLE 10—SHARPS INJURY BY WORK PROCESS (N =1345)

Work Process	Number of Injuries Reported	Percent of Injuries Reported
During use of sharp	399	29.7
After use & before disposal of sharp	312	23.2
Sharp left, inappropriate place (table, bed, etc.)	219	16.3
While putting sharp into disposal container	144	10.7
During cleaning	94	7.0
During recapping or as a result of recapping	80	5.9
During the process of removing needles	27	2.0
During transfer of blood to tubes	27	2.0
Disassembling or assembling	24	1.8
Other (e.g., passing sharp instrument to co-worker)	19	1.4
Total	1345	100.0

TABLE 11–SHARPS INJURY BY DEPARTMENT LOCATION (N =1455)

Department Location	Number of Injuries Reported	Percent of Injuries Reported
Patient room	361	24.8
Operating room/Surgery center	272	18.7
Emergency Dept.	145	10.0
CCU/ICU/NICU/Telemetry	111	7.6
Clinical Laboratory	104	7.1
Other	103	7.1
Medical/outpatient clinic	99	6.8
Procedure room/X-ray	97	6.7
Labor & Delivery/Perinatal area	63	4.3
Patient Home	38	2.6
Service/utility area	41	2.8
Nurses station/hallway/med room	21	1.4
Total	1455	100.0

TABLE 12–TYPE OF DEVICE CAUSING SHARP INJURY (N = 1643)

Type of Device	Number Reporting	Percent Reporting
Disposable needle/syringe	490	29.8
Needle, coder not sure what kind	264	16.1
Suture needle	133	8.1
IV catheter stylet & heparin locks	133	8.1
Winged steel needle for blood drawing or IV set	115	7.0
Scalpel (disposable & reusable) & other blades	85	5.2
Vacuum tube blood collection needle & holder	76	4.6
Other sharp item	67	4.1
Lancet	52	3.2
Other needle, including Huber	46	2.8
Needle, reporting agency not sure	42	2.6
Surgical-related devices	29	1.8
Razor, scissors, staples, sutures	28	1.7
Blood gas syringe	27	1.6
Needle on IV line	27	1.6
Pre-filled syringe with needle	16	1.0
Glass items	14	<1.0
Total	1643	100.0

TABLE 13–DID DEVICE INVOLVED IN INJURY HAVE ENGINEERED SHARPS INJURY PROTECTION? (N = 832)

Engineered Sharps Injury Protection	Number	Percent
No	585	70.3
Yes	170	20.4
Don't know	77	9.3
Total	832	100.0

TABLE 14–INJURED EMPLOYEE HAVE AN OPINION AS TO WHETHER OR NOT AN ENGINEERED SHARPS INJURY PROTECTIVE DEVICE COULD OR WOULD HAVE PREVENTED THE INJURY? (N = 491)

Employee Opinion #1	Number	Percent
Yes	327	66.6
No	164	33.4
Total	491	100.0

TABLE 15—CATEGORIZATION OF EMPLOYEE OPINIONS REGARDING ENGINEERED SHARPS INJURY PROTECTION (N = 191)

Opinion Regarding Engineered Sharps Injury Protection	Number of Opinions Offered	Percent of Opinions Reported
Sharps device would/could have prevented injury	119	62.3
Safety device was used, but design modifications needed	14	7.3
Safety device could not have prevented injury	15	7.9
Safety device was in stock, but not used	9	4.7
Safety device on trial/ordered/ or otherwise not available	9	4.7
Device had safety device, but it was not yet activated	9	4.7
Safety device would hinder procedure	5	2.6
Thought no safety device was available	6	3.1
Other	5	2.6
Total	191	100.0

TABLE 16—DID INJURED EMPLOYEE HAVE AN OPINION AS TO WHETHER ANOTHER ENGINEERING, ADMINISTRATIVE OR WORK CONTROL WOULD HAVE PREVENTED THE INJURY? (N = 474)

Employee Opinion #2	Number	Percent
Yes	350	73.8
No	124	26.2
Total	474	100.0

TABLE 17–CATEGORIZATION OF EMPLOYEE OPINIONS REGARDING OTHER CONTROLS (N = 311)

Opinion Regarding Other Work Controls	Number of Opinions Offered	Percent of Opinions Reported
Human behavior change/human factors	117	37.6
Proper sharps disposal	62	19.9
Improved sharps disposal container design or contained placement or sharps container too full	25	8.0
Revised procedures/ improved procedure or protocol	22	7.1
Improved staffing and/or training	18	5.8
Avoid recapping	16	5.1
Other design feature or improved design of non-sharps tools or PPE	14	4.5
Move slower or slow down	11	3.5
Availability of another co-worker to assist with procedure	10	3.2
Revised patient care protocols	7	2.3
Availability of equipment	5	1.6
Other	4	1.3
Total	311	100.0

Facility Survey Data (Tables 18 - 29)

TABLE 18–FACILITY ABILITY TO PROVIDE DATA

Is Your Facility Able to Provide Data at This Time?

	All Cases	%	Hospitals	%	HHA	%	SNF	%
No	429	34.4	37	13.5	139	37.9	253	41.9
Yes	221	17.7	59	21.5	64	17.4	98	16.2
Not Sure	428	34.3	157	57.1	112	30.5	159	26.3
Missing	168	13.5	22	8.0	52	14.2	94	15.6
Total	1246	100.0	275	100.0	367	100.0	604	100.0

TABLE 19–FORMAT OF SHARPS INJURY RECORD BY FACILITY TYPE

Format of Sharps Log	Hospitals % (N=287)	SNFs % (N=614)	HHAs % (N=373)
Written Records only	70	96	89
Electronic Records only	6	<1	1
Written and Electronic Records	22	1	6
Not Answered	2	3	4

TABLE 20—FORMS USED TO RECORD SHARPS INJURY DATA BY FACILITY TYPE

Type of Form Used	Hospitals % (N=287)	SNFs % (N=614)	HHAs % (N=373)
OSHA Log 200	70	43	41
Sharps Injury Log	66	33	37
Form 5020	34	25	25
Doctor's First Report	40	16	17
Medical Record	61	29	36
Other Form	25	28	41

Note: Facilities may use more than one type of form

TABLE 21—DEPARTMENT THAT KEEPS SHARPS INJURY DATA

Department Keeping Data	All Facilities(%) N=1274	Hospitals(%) N=386	SNFs(%) N=723	HHAs(%) N=432
Infection Control	624 (49)	118 (31)	362 (50)	144 (33)
Employee Health	501 (39)	214 (55)	168 (23)	119 (28)
Other	416 (32)	54 (14)	193 (27)	169 (39)

Note: Facilities may keep records in more than one department.

TABLE 22—REQUEST FOR EDUCATIONAL MATERIAL**WOULD YOU LIKE TO RECEIVE EDUCATIONAL MATERIALS FROM THE SHARPS PROGRAM?**

		%	Hospitals	% of Hospitals	HHAs	% of HHAs	SNF	% of SNFs
No	77	6	19	7	28	7	30	5
Yes	1087	85	253	88	316	85	518	84
Not Sure	63	5	4	1	21	6	38	6
Not Answered	47	4	11	4	8	2	28	5
Total	1274	100.0	287	100.0	373	100.0	614	100.0

TABLE 23—TESTING SHARPS INJURY PREVENTION DEVICES**Has Your Facility Tested Any Sharps Injury Prevention Devices?**

	All Cases	%	Hospitals	%	HHA	%	SNF	%
No	734	58	45	16	261	70	428	70
Yes	509	40	239	83	101	27	169	27
Not Answered	31	2	3	1	11	3	17	3
Total	1274	100.0	287	100.0	373	100.0	614	100.0

TABLE 24—PERCENT USING SAFETY DEVICES BY FACILITY TYPE

Type of Safety Device Used	All Facilities Combined (%)	Hospitals (%)	Skilled Nursing Facilities (%)	Home Health Agencies (%)
Needles or Needleless Injection Systems	66	64	71	58
Blood Collection Devices	45	69	18	71
Needleless IV Systems	68	88	61	64
Lancets	69	72	72	60

TABLE 25—SAFETY INJECTION SYSTEMS USED BY FACILITY TYPE
N=Number of Facilities that Use Specified Product

Safety Needles&Syringes & Needleless Injection Systems	All Facilities N (%)	Hospitals N (%)	HHAs N (%)	SNFs N (%)
Entrap syringe (MedTech Group)	8 (1)	-	3 (1)	5 (1)
Safety Lok Syringe (Becton Dickinson (BD))	408 (32)	97 (34)	118 (32)	193 (31)
Safety Glide Shielding Injection needle (BD)	144 (11)	50 (17)	42 (11)	52 (9)
Monoject Syringe (Sherwood Medical)	471 (37)	60 (21)	110 (29)	301 (49)
Needle-Pro (Sims-Portex)	41 (3)	20 (6)	6 (2)	15 (2)
Targett Transdermal Injection Appliance & Stykguard needle (Cutting Edge Technologies)	2 (<1)	-	-	2 (<1)
Vanish Point Syringe (Retractable Technologies)	45 (4)	24 (8)	9 (2)	12 (2)
Maxxon Safety Syringe (Maxxon, Inc.)	2 (<1)	-	1 (<1)	1 (<1)
Needle-free Injection Management System (Bioject)	51 (4)	5 (2)	23 (6)	23 (4)
Safe-1 Safety Syringe (Safety 1st Medical)	3 (<1)	-	1 (<1)	2 (<1)
Others: "Luer Lok"	20 (2)	1 (<1)	6 (2)	13 (2)
Others	26 (2)	4 (1)	10 (3)	12 (2)

TABLE 26—SAFETY BLOOD COLLECTION DEVICES USED BY FACILITY TYPE
N=Number of Facilities that Use Specified Product

Blood Collection Devices	All Facilities N (%)	Hospitals N (%)	HHAs N (%)	SNFs N (%)
Punctur Guard (Bioplexus)	37 (3)	21 (7)	8 (2)	8 (1)
Safety-Lok blood collection sets (BD)(Vacutainer (Vac))	283 (22)	128 (45)	117 (31)	38 (6)
Pro-ject Blood Collection multi-sample needle (Pro-Tec)	6 (<1)	1 (<1)	2 (<1)	3 (<1)
Saf-T Clik Shielded blood needle adapter (Winfield Med)	20 (2)	5 (2)	10 (3)	5 (1)
Proguard II vacuum tube holder (Care Med Devices)	15 (1)	3 (1)	8 (2)	4 (1)
Safe Point Needle Cover System (North American Med products)	8 (1)	1 (<1)	4 (1)	3 (<1)
Blood Collection and transfer tube holders (Sherwood Monoject (SM))	64 (5)	15 (5)	36 (10)	17 (3)
Vacutainer Plus Plastic Tubes (BD)	312 (24)	72 (25)	187 (50)	53 (9)
Vanish Point vacuum tube holder (RT)	14 (1)	8 (3)	4 (1)	2 (<1)
Angel Wing butterfly needle (SM)	121 (10)	21 (7)	72 (19)	28 (5)
Punctur Guard winged set (Bioplexus)	5 (<1)	1 (<1)	3 (1)	1 (<1)
Shamrock Blood Collection (Winfield Med)	11 (1)	3 (1)	7 (2)	1 (<1)
Other: "Eclipse Blood Collection Needle" (BD)	2 (<1)	2 (1)	-	-
Other: "Venipuncture Needle-Pro" (Sims)	21 (2)	17 (6)	4 (1)	-
Other: "Vacutainer" (BD or other manufacturer)	13 (1)	5 (2)	7 (2)	1 (<1)
Others	18 (1)	8 (2)	6 (1)	4 (<1)

* Note: Facilities may use multiple products in a category.

TABLE 27–SAFETY INTRAVENOUS PRODUCTS AND CATHETERS USED BY FACILITY TYPE

N=Number of Facilities that Use Specified Product

IV Products & Catheters	All Facilities- N (%)	Hospitals- N (%)	HHAs N (%)	SNFs N (%)
Stick Guard (Intl Medication Systems)	10 (1)	-	4 (1)	6 (1)
Centurion Kleen Needle System (TSHSC)	9 (1)	4 (1)	2 (<1)	3 (<1)
Click Lock (ICU Medical)	95 (7)	13 (4)	22 (6)	60 (10)
Clave Connector (ICU Medical)	241(19)	53 (19)	74 (20)	114 (19)
Safesite needleless I.V. system (Braun)	144 (11)	20 (7)	50 (13)	74 (12)
Needle-free dispensing systems (Braun)	71 (6)	8 (3)	16 (4)	47 (8)
Interlink IV Access and Injection Site systems (BD/Baxter)	424 (33)	112 (39)	141 (38)	171 (28)
Atrium I.V. Maintenance System(BD)	7 (1)	1 (<1)	2 (<1)	4 (1)
Lifeshield IV Administration System (Abbott Laboratories)	59 (5)	27 (9)	13 (4)	19 (3)
Protectiv IV Catheter (Johnson & Johnson)	104 (8)	73 (25)	21 (6)	10 (2)
Insyte Autoguard shielded IV catheter (BD)	254 (20)	60 (21)	51 (14)	143 (23)
Saf-T-Intima IV Catheter System (BD)	87 (7)	37 (13)	14 (4)	36 (6)
Others: "Safeline" Needle-Free (B. Braun)	4 (<1)	4 (1)	-	-
Others: "Smartsite "Needleless Valve (Alaris)	19 (2)	11 (4)	5 (1)	3(1)
Others: "Ultrasite" Valve (B. Braun)	6 (1)	-	-	6 (1)
Others: "Luer Lok"	3 (<1)	-	-	3 (<1)
Others	98 (8)	24 (8)	54 (15)	45 (7)

* Note: Facilities may use multiple products in a category.

TABLE 28—SAFETY LANCETS USED BY FACILITY TYPE
N=Number of Facilities that Use Specified Product

Lancets	All Facilities N (%)	Hospitals N (%)	HHAs N (%)	SNFs N (%)
Glucollet 2 (Miles)	202 (16)	36 (12)	81 (22)	85 (14)
Tenderlett (Int'l Technidyne Corp.)	77 (6)	51 (18)	21 (6)	5 (1)
Unistik (Owen Mumford)	122 (10)	61 (21)	36 (10)	25 (4)
Cleanlet Lancets	83 (6)	6 (2)	36 (10)	41 (7)
Quick Heel Safety Lancet (BD)	81 (6)	36 (12)	27 (7)	18 (3)
Others: "Haemolance" Lancet Chonimed	246 (19)	5 (2)	2 (<1)	239 (39)
Others: "Microtainer" lancet (Genie or other) (BD)	28 (2)	23 (8)	5 (1)	-
Others: "Monolettor" lancet (Kendall)	7 (<1)	-	-	7 (1)
Others: "Saf-T-Pro" (Roche)	25 (2)	15 (5)	7 (2)	3 (<1)
Others: "Tenderfoot" (ITC)	41 (3)	25 (9)	15 (4)	1 (<1)
Others	115 (9)	19 (7)	44 (12)	52 (8)

* Note: Facilities may use multiple products in a category.

TABLE 29–WILLINGNESS TO PARTICIPATE IN PROGRAM ACTIVITIES**WILLING TO PARTICIPATE?**

	All Cases	%	Hospitals	%	HHA	%	SNF	%
No	228	18.3	25	9.1	85	23.2	118	19.5
Yes	419	33.6	110	40.0	114	31.1	195	32.3
Not Sure	401	32.2	92	33.5	115	31.3	194	32.1
Missing	198	15.9	48	17.5	53	14.4	97	16.1
Total	1246	100.0	275	100.0	367	100.0	604	100.0

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VIII. APPENDICES

APPENDIX 1: THE CALIFORNIA LIST OF NEEDLELESS SYSTEMS

APPENDIX 2: SAMPLE SHARPS INJURY CONTROL LOG

APPENDIX 3: SHARPS INJURY PROGRAM FACILITY SURVEY FORMS

APPENDIX 4: SURVEY FORMS MANUFACTURERS

APPENDIX 5: DEVICE EVALUATION RESOURCES

APPENDIX 6: BLOODBORNE PATHOGENS CHECKLIST

APPENDIX 7: FACT SHEET: HEPATITIS C

APPENDIX 8: SHARPS PROGRAM BROCHURE

APPENDIX 9: CALIFORNIA MORBIDITY ARTICLE

APPENDIX 10: PARTIAL LISTING OF PRESENTATIONS

Note: To obtain a copy of the Appendices, please write to

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